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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,245	11/14/2001	Alex Burgin	00-1206-B	7743

26389 7590 06/18/2004

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/993,245		BURGIN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	David J Steadman		1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Status of the Application***

- [1]** Claims 1-27 are pending in the application.
- [2]** Receipt of information disclosure statements (IDSs), filed October 21, 2002, November 18, 2002, and November 29, 2002, is acknowledged.

### ***Election/Restrictions***

- [3]** Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to a crystal composition comprising a ternary complex of a compound, a protein, and a polynucleotide, and optionally wherein the crystal structure is Form 7, classified in class 435, subclass 233.
  - II. Claims 1-9, drawn to a crystal composition comprising a ternary complex of a compound, a protein, and a polynucleotide, and optionally wherein the crystal structure is Form 8, classified in class 435, subclass 233.
  - III. Claims 1-9, drawn to a crystal composition comprising a ternary complex of a compound, a protein, and a polynucleotide, and optionally wherein the crystal structure is Form 9, classified in class 435, subclass 233.
  - IV. Claims 1-9, drawn to a crystal composition comprising a ternary complex of a compound, a protein, and a polynucleotide, and optionally wherein the crystal structure is Form 10, classified in class 435, subclass 233.

- V. Claims 1-9, drawn to a crystal composition comprising a ternary complex of a compound, a protein, and a polynucleotide, and optionally wherein the crystal structure is Form 11, classified in class 435, subclass 233.
- VI. Claim 10 and 24, drawn to a three-dimensional structure of human topoisomerase I in complex with duplex DNA (Form 7) and the use of a topoisomerase and DNA to crystallize and determine the 3-D structure of a DNA binding agent, classified in class 702, subclass 27.
- VII. Claims 11-12 and 24, drawn to a three-dimensional structure of a compound contacting human topoisomerase I in covalent complex with duplex DNA and optionally wherein the compound is topotecan in the crystal Form9-TTC and the use of a topoisomerase and DNA to crystallize and determine the 3-D structure of a DNA binding agent, classified in class 702, subclass 27.
- VIII. Claims 11, 13, and 24, drawn to a three-dimensional structure of a compound contacting human topoisomerase I in covalent complex with duplex DNA and optionally wherein the compound is AG260 in the crystal Form9-AG260 and the use of a topoisomerase and DNA to crystallize and determine the 3-D structure of a DNA binding agent, classified in class 702, subclass 27.
- IX. Claims 11, 14, and 24, drawn to a three-dimensional structure of a compound contacting human topoisomerase I in covalent complex with duplex DNA and optionally wherein the compound is MJ-II-38 in the

Art Unit: 1652

crystal Form 10 and the use of a topoisomerase and DNA to crystallize and determine the 3-D structure of a DNA binding agent, classified in class 702, subclass 27.

- X. Claims 11, 15, and 24, drawn to a three-dimensional structure of a compound contacting human topoisomerase I in covalent complex with duplex DNA and optionally wherein the compound is Hoechst-33342 in the crystal Form 11 and the use of a topoisomerase and DNA to crystallize and determine the 3-D structure of a DNA binding agent, classified in class 702, subclass 27.
- XI. Claims 18 and 20-23, drawn to novel compounds that complex and form a crystal structure and novel inhibitors of topoisomerase, classified in class 514, subclass 789.
- XII. Claims 25-27, drawn to a crystallant solution, classified in class 436, subclass 85.
- XIII. Claims 16-17 and 19, drawn to a method for identifying an agent which is an inhibitor of human topoisomerase I and a process for designing an inhibitor of a topoisomerase, classified in class 702, subclass 27.

**[4]** The inventions are distinct, each from the other because:

**[5]** The crystal compositions of Groups I-V comprise structurally distinct molecules and no single crystal of Groups I-V would render the others obvious to one of ordinary skill in the art.

[6] The 3-D structures of Groups VI-X comprise different combinations of molecules resulting in distinct crystal forms and no single 3-D structure of Groups VI-X would render the others obvious to one of ordinary skill in the art.

[7] The crystal compositions of Groups I-V, the 3-D structures of Groups VI-X, the compounds of Group XI, and the crystallant solution of Group XII are structurally and chemically distinct entities, capable of separate manufacture, use, and effect.

[8] The crystals of Groups I-V, the 3-D structures of Groups VI-X, the compound of Group XI, and the crystallant solution of Group XII are related to the method of Group XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). With respect to Groups I-X and XII, topoisomerase inhibitors can be identified by screening the compounds in an in vitro inhibitor assay and a topoisomerase inhibitor can be designed by similarity to other topoisomerase inhibitors. Regarding Group XI, it is noted that the compound can be used as an affinity purification reagent for purification of a topoisomerase polypeptide.

[9] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XIII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the

examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search. Each of the inventions requires a separate patent and non-patent literature search requiring a different text search for each Group and thus, co-examination of the inventions of Groups I-XIII would require a serious burden on the examiner.

[10] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[11] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

[12] It is noted that claim 1-9, 11, and 24 have been included in multiple groups. The claims will be examined only to the extent that they read on the elected subject matter.

### ***Rejoinder***

[13] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise

Art Unit: 1652

include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116;

amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571)



Art Unit: 1652

272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman  
Patent Examiner  
Art Unit 1652

*06-09-04*